



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0277]

Guidance for Industry on Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." This guidance is intended to help small entities and other stakeholders comply with FDA's regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the

SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Office of Compliance and Enforcement, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877-287-1373, ctpcompliance@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111–31; 123 Stat. 1776) was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) and providing FDA with authority to regulate tobacco products. Section 102 of the Tobacco Control Act requires FDA to publish final regulations regarding cigarettes and smokeless tobacco which are identical in their provisions to the regulations issued by FDA on August 28, 1996 (61 FR 44396), with certain specified exceptions. In the Federal Register of March 19, 2010 (75 FR 13225), FDA published its final regulations entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," codified at 21 CFR part 1140. The final regulations apply to manufacturers, distributors, and retailers who manufacture, distribute, or sell cigarettes or smokeless tobacco products.

These regulations took effect on June 22, 2010, and impose restrictions on sales and distribution, including youth access, and advertising and labeling of cigarettes, including roll-your-own tobacco, cigarette tobacco, and smokeless tobacco. For instance, retailers are: Prohibited from selling cigarettes, including roll-your-own tobacco, cigarette tobacco, or smokeless tobacco to persons under the age of 18; required to verify the age of all customers

under the age of 27 by checking a photographic identification that includes the bearer's date of birth; and prohibited from distributing free samples of cigarettes.

FDA announced the publication of a draft guidance document on this subject on June 9, 2010 (75 FR 32791), and issued a revised draft guidance on March 23, 2011 (76 FR 16424), to remove potential ambiguities and address several issues not included in the original draft guidance. In response to comments submitted to the public docket, at stakeholder meetings, and in calls from the public, FDA has provided additional clarifying examples to assist in complying with part 1140.

II. Significance of Guidance

FDA is issuing this guidance document consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on "Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

An electronic version of the guidance document is available on the Internet at

<http://www.regulations.gov> and

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: August 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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